



DOCKET NO: C1039.70077US00

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Arthur M. Krieg, et al.  
Serial No: 10/619,279  
Confirmation No: 8248  
Filed: July 14, 2003  
For: IMMUNOSTIMULATORY NUCLEIC ACID  
MOLECULES

Examiner: Not yet assigned  
Art Unit: 1632

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CERTIFICATE OF MAILING UNDER 37 C.F.R. §1.8(a)

The undersigned hereby certifies that this document is being placed in the United States mail with first-class postage attached, addressed to Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the 0 day of January, 2004.

Helen C. Lockhart, Ph.D., Reg. No. 39,248

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Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

SUPPLEMENTAL STATEMENT FILED PURSUANT TO THE DUTY OF  
DISCLOSURE UNDER 37 CFR §§1.56, 1.97 AND 1.98

Sir:

Pursuant to the duty of disclosure under 37 C.F.R. §§1.56, 1.97 and 1.98, the Applicant requests consideration of this Information Disclosure Statement.

Compliance with 37 C.F.R. §1.97

This Information Disclosure Statement has been filed before the mailing date of a first Office Action on the merits in the above-identified case.

No fee or certification is required.

Information Cited

The Applicant hereby makes of record in the above-identified application the information listed on the attached form PTO-1449 (modified). The order of presentation of the references should not be construed as an indication of the importance of the references.

The Applicant hereby makes the following additional information of record in the above-identified application.

Serial No. 10/619,279

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2. The enclosed form PTO-1449 be signed by the Examiner to evidence that the cited information has been fully considered by the Patent and Trademark Office during the examination of this application;
3. The citations for the information be printed on any patent which issues from this application.

By submitting this Information Disclosure Statement, the Applicant makes no representation that a search has been performed, of the extent of any search performed, or that more relevant information does not exist.

By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, material to patentability as defined in 37 C.F.R. §1.56(b).

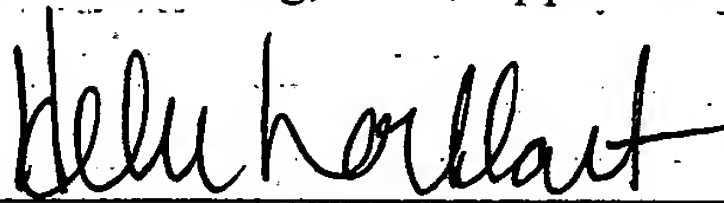
By submitting this Information Disclosure Statement, the Applicant makes no representation that the information cited in the Statement is, or is considered to be, in fact, prior art as defined by 35 U.S.C. §102.

Notwithstanding any statements by the Applicant, the Examiner is urged to form his own conclusion regarding the relevance of the cited information.

An early and favorable action is hereby requested.

Respectfully submitted,  
Arthur M. Krieg, et al., *Applicant*

By:

  
Helen C. Lockhart, Ph.D., Reg. No. 39,248  
Wolf, Greenfield & Sacks, P.C.  
600 Atlantic Avenue  
Boston, Massachusetts 02210-2211  
Telephone: (617) 720-3500

Docket No. C1039.70077US00  
Date: January 6, 2004  
XNDDX

Serial No.: 40/619,279

Art Unit: 1632

The applicant would like to bring to the Examiner's attention the following co-pending applications that may contain subject matter related to this application (copies enclosed):

Docket Number	Serial Number	Filing Date	Inventor(s)
C1037.70013US00	09/776,479	2/2/01	Bratzler et al.
C1037.70016US00	09/009,634	1/20/98	Hutcherson et al.
C1037.70019US00	09/920,313	8/1/01	Bratzler et al.
C1037.70021US00	09/949,194	9/7/01	Peterson et al.
C1037.70025US00	10/017,995	12/14/01	Bratzler
C1037.70038US01	10/735,592	12/11/03	Krieg et al.
C1037.70041US00	10/613,749	7/3/03	Krieg
C1037.70042US00	10/613,524	7/3/03	Krieg
C1037.70043US00	10/613,739	7/3/03	Krieg
C1037.70044US00	10/613,716	7/3/03	Krieg
C1037.70045US00	10/613,228	7/3/03	Krieg
C1037.70046US00	10/445,247	6/5/03	Krieg
C1037.70048US00	10/644,052	8/19/03	Krieg et al.
C1037.70049US00	10/643,141	8/18/03	Hutcherson et al.
C1037.70051US00	10/666,733	9/19/03	Bratzler et al.
C1037.70052US00	10/668,050	9/22/03	Bratzler et al.
C1039.70020US00	09/337,584	6/21/99	Krieg et al.
C1039.70021US01	10/719,493	11/21/03	Krieg et al.
C1039.70022US00	09/337,893	6/21/99	Krieg
C1039.70035US00	09/669,187	09/25/00	Krieg et al.
C1039.70036US00	09/559,140	4/27/00	Noll et al.
C1039.70041US00	09/655,319	9/5/00	Krieg et al.
C1039.70042US00	09/630,319	7/31/00	Krieg et al.
C1039.70043US00	09/629,477	7/31/00	Krieg et al.
C1039.70044US00	09/672,126	9/27/00	Hartmann et al.
C1039.70048US00	09/818,918	3/27/01	Krieg et al.
C1039.70049US00	09/824,468	04/02/01	Krieg et al.
C1039.70052US00	09/888,326	6/22/01	Weiner et al.
C1039.70057US00	09/965,101	9/26/01	Davis et al.
C1039.70058US00	10/023,909	12/18/01	Davis et al.
C1039.70060US00	10/112,653	3/29/02	Krieg et al.
C1039.70061US00	10/161,229	6/3/02	Krieg et al.

Serial No. 10/619,279

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Docket Number	Serial Number	Filing Date	Inventor(s)
C1039.70062US00	10/187,489	7/2/02	Krieg et al.
C1039.70063US00	10/224,523	8/19/02	Krieg et al.
C1039.70065US00	10/272,502	10/15/02	Krieg et al.
C1039.70067US00	10/300,247	11/20/02	Davis et al.
C1039.70068US00	10/306,522	11/27/02	Krieg et al.
C1039.70069US00	10/314,578	12/9/02	Krieg et al.
C1039.70070US00	10/382,822	3/6/03	Krieg et al.
C1039.70071US00	10/435,656	5/9/03	Krieg et al.
C1039.70072US00	10/434,696	5/9/03	Davis et al.
C1039.70073US00	TBD	12/22/03	Krieg et al.
C1039.70075US00	10/613,916	7/3/03	Krieg et al.
C1039.70078US00	10/627,331	7/25/03	Krieg et al.
C1039.70079US00	10/627,413	7/25/03	Krieg et al.
C1039.70082US00	10/631,676	7/30/03	Krieg et al.
C1039.70083US00	10/690,495	10/21/03	Krieg
C1039.70084US00	10/649,584	8/25/03	Krieg et al.
C1040.70006US00	09/316,199	5/21/99	McCluskie et al.
C1040.70010US00	09/768,012	1/22/01	Davis et al.
C1041.70002US00	09/241,653	2/2/99	Wagner et al.
C1041.70005US00	09/355,254	7/23/99	Wagner et al.
C1041.70010US00	09/786,436	9/3/99	Wagner et al.
C1041.70014US00	09/895,007	6/28/01	Schetter et al.
C1041.70016US00	09/954,987	9/17/01	Bauer et al.
C1041.70019US00	10/140,013	5/6/02	Schetter et al.
C1041.70029US00	10/212,133	8/1/02	Lipford et al.
C1041.70031US00	10/265,072	10/5/02	Lipford
C1041.70035US00	10/373,381	2/24/03	Wagner et al.
C1041.70037US00	10/407,952	4/4/03	Lipford et al.

#### Remarks

Documents cited anywhere in the Information Disclosure Statement are enclosed unless otherwise indicated. It is respectfully requested that:

1. The Examiner consider completely the cited information, along with any other information, in reaching a determination concerning the patentability of the present claims;

FORM PTO-1449/A and B (Modified)

**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

APPLICATION NO.: 10/619,279

ATTY. DOCKET NO.: C1039.70077US00

FILING DATE: July 14, 2003

CONFIRMATION NO.: 8248

APPLICANT: Arthur M. Krieg, et al.

GROUP ART UNIT: 1632

EXAMINER: Not yet assigned

Sheet 1 of 4

**U.S. PATENT DOCUMENTS**

Examiner's Initials.	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	*	5,417,972		Bhat et al.	05/23/1995
	*	5,445,938		Hanai et al.	08/29/1995
	*	5,491,088		Hellstrom et al.	02/13/1996
	*	5,679,647	B1	Carson et al.	10/21/1997
	*	5,756,097		Landucci et al.	05/26/1998
	*	5,780,448	B1	Davis	07/14/1998
	*	5,837,243		Deo et al.	11/17/1998
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	**	US 2002/0156033	A1	Raz et al.	10/24/2002
	**	US 2003/0049266	A1	Bratzler et al.	03/13/2003
	**	US 2003/0050263	A1	Fearon et al.	03/13/2003
	**	US 2003/0078223	A1	Krieg et al.	04/24/2003
	**	US 2003/0092663	A1	Raz et al.	05/15/2003
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	**	US 2003/0199466	A1	Fearon et al.	10-23-2003



CANCELED

JAN 09 2004

<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/619,279		ATTY. DOCKET NO.: C1039.70077US00	
				FILING DATE: July 14, 2003		CONFIRMATION NO.: 8248	
				APPLICANT: Arthur M. Krieg, et al.			
				GROUP ART UNIT: 1632		EXAMINER: Not yet assigned	
Sheet	2	of	4				

**U.S. PATENT DOCUMENTS**

Examiner's Initials	Cite No.	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication or of issue of Cited Document MM-DD-YYYY
		Number	Kind Code		
	**	US 2003/0212028	A1	Raz et al.	11-13-2003
	**	US 2003/0216340	A1	Van Nest et al.	11-20-2003

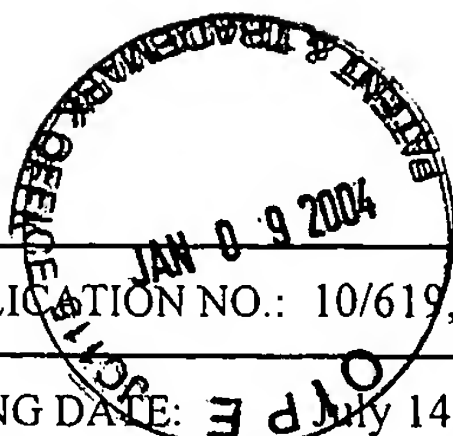
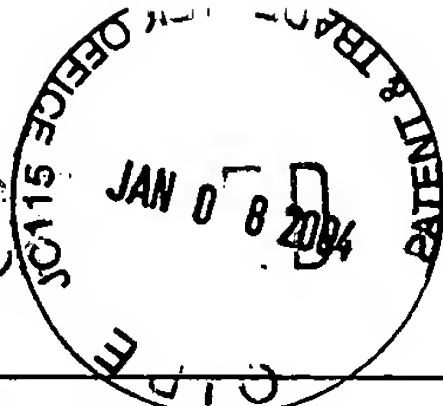
**FOREIGN PATENT DOCUMENTS**

Examiner's Initials	Cite No.	Foreign Patent Document			Name of Patentee or Applicant of Cited Document (not necessary)	Date of Publication of Cited Document MM-DD-YYYY	Translation (Y/N)
		Office/ Country	Number	Kind Code			
	*	WO	96/02560	A1	University of NC at Chapel Hill	02/01/1996	
	B1	WO	99/62923	A2	Dynavax Tech. Corp	12/09/1999	
	B2	WO	00/20039	A1	Regents of the University of CA	04/13/2000	
	B3	WO	00/62787	A1	Regents of the University of CA	10/26/2000	

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	*	AGGARWAL, S.K. et al., "Cell-Surface-Associated Nucleic Acid in Tumorigenic Cells Made Visible with Platinum-Complexes by Electron Microscopy", <i>Proc. Nat. Acad. Sci. USA</i> , March 1975, Pages 928-932, Vol. 72, No. 3		
	*	BERNHARD, M., et al., "Monocyte Macrophage Mediated Antibody Dependent and Independent Cell Mediated Cytotoxicity in Normals and Cancer Patients, ABSTRACT, Proceedings of AACR and ASCO, 22:372, c-159		
	*	COHEN, J., et al., "IL-12 Deaths: Explanation and a Puzzle", <i>Science</i> , 10:270:5238:908		
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	*	HARTMANN, G., et al., "CpG DNA: A potent signal for growth, activation, and maturation of human dendritic cells", <i>Proc. Natl. Acad. Sci.</i> , 96:9305-9310, (1999)		
	*	KATAOKA, T., et al. "Immunotherapeutid potential in Guinea-Pig Tumor Model of Deoxyribonucleic Acid From Mycobacterium Bovix BCG Complexed with Poly-L-Lysine and Carboxy-Methylcellulose", <i>Jpn J. Med. Sci. Biol.</i> 43:171-182, (1990)		
	*	KLINMAN, D.M. et al., "Contribution of CpG Motifs to the Immunogenicity of DNA Vaccines", <i>J. of Immunol.</i> , 1997, Pages 3635-3639, Vol. 158, No. 8, The American Association of Immunologists		
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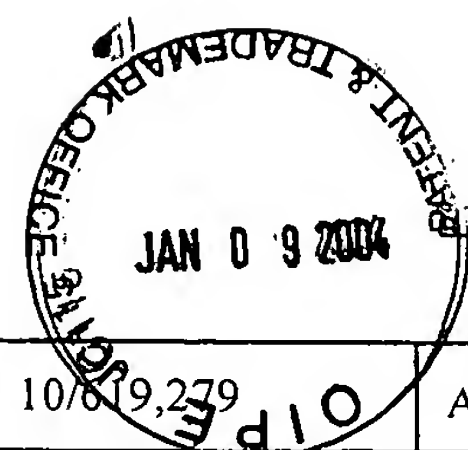
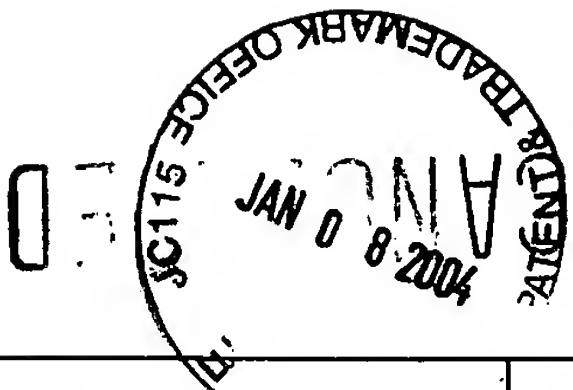
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FORM PTO-1449/A and B (Modified)				APPLICATION NO.: 10/619,279		ATTY. DOCKET NO.: C1039.70077US00			
INFORMATION DISCLOSURE STATEMENT BY APPLICANT				FILING DATE: May 14, 2003		CONFIRMATION NO.: 8248			
				APPLICANT: Arthur M. Krieg, et al.					
				GROUP ART UNIT: 1632		EXAMINER: Not yet assigned			
Sheet	3	of	4						

OTHER ART — NON PATENT LITERATURE DOCUMENTS

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)
	*	KURAMOTO, et al., "In Situ Infiltration of Natural Killer-Like Cell Induced by Intradermal Injection of the Nucleic Acid Fraction from BCG", <i>Microbiol. Immunol.</i> , 33:11:929-940, (1989)	
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	*	Lacour, J., et al., "Clinical Trials Using Polyadenylic-Polyuridylic Acid as an Adjuvant to Surgery in Treating Different Human Tumors, <i>J of Biological Response Modifiers</i> , 4:538-543, (1985)	
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	*	REISFELD, R., et al., "Monoclonal Antibodies in Cancer Therapy", <i>Clinics in Laboratory Medicine</i> , 12:2:201-216, (1992)	
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	*	SHIMADA, S., et al., "In Vivo Augmentatio of Natural Killer Cell Activity With A Deoxyribonucleic Acid Fraction of BCG", <i>Jpn J. Cancer Res.</i> , 77:808-816, (1986)	
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<b>FORM PTO-1449/A and B (Modified)</b>  <b>INFORMATION DISCLOSURE STATEMENT BY APPLICANT</b>				APPLICATION NO.: 10/619,279		ATTY. DOCKET NO.: C1039.70077US00	
				FILING DATE: July 14, 2003		CONFIRMATION NO.: 8248	
				APPLICANT: Arthur M. Krieg, et al.			
				GROUP ART UNIT: 1632		EXAMINER: Not yet assigned	
Sheet	4	of	4				

**OTHER ART — NON PATENT LITERATURE DOCUMENTS**

Examiner's Initials	Cite No	Include name of the author (in CAPITAL LETTERS) title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, relevant page(s), volume-issue number(s), publisher, city and/or country where published.	Translation (Y/N)	
	*	WILTROUT, R.H., et al., "Immunomodulation of Natural Killer Activity by Polyribonucleotides", <i>Journal of Biological Response Modifiers</i> , 1985, Pages 512-517, Vol. 4, No. 5, New Raven Press, NY		
	*	WOOLDRIDGE, J., et al., "Immunostimulatory Oligodeoxynucleotides Containing CpG Motifs Enhance the Efficacy of Monoclonal Antibody Therapy of Lymphoma", <i>Blood</i> , 89:8:2994-2998, (1997)		
	*	WOOLDRIDGE, J.E. et al., "Select Unmethylated CpG Oligodeoxynucleotides Improve Antibody Dependent Cellular Cytotoxicity <i>in Vitro</i> of Both Murine and Human B Cell Lymphomas", <i>Blood</i> , December 1995, Page 2877, Abstract, Vol. 86		
	*	WOOLDRIDGE, J.E. et al., "Select unmethylated CpG oligodeoxynucleotide improve antibody dependent cellular cytotoxicity <i>in vitro</i> and <i>in vivo</i> ", Proceedings of the American Association for Cancer Research #3253, March 1996, Page 477, Abstract, Vol. 37		

EXAMINER	DATE CONSIDERED
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#EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

\*a copy of this reference is not provided as it was previously cited by or submitted to the office in one of the prior applications, Serial No. 08/386,063, filed February 7, 1995, Serial No. 08/738,652, filed October 30, 1996, Serial No. 09/337,619, filed June 21, 1999, and relied upon for an earlier filing date under 35 U.S.C. 120 (continuation, continuation-in-part, and divisional applications).

\*\* copies of these patents and patent applications are not enclosed pursuant to the waiver by the USPTO of the requirement under 37 C.F.R. 1.98 (a)(2)(i) for patent applications filed after June 30, 2003.

[NOTE - Must provide a copy of any patent, publication, other information listed, even if it was previously submitted to, or cited by, the U.S. Patent Office in an earlier application, unless the earlier application is identified by the IDS and is relied upon for an earlier filing date under 35 U.S.C. §120, and the copy was provided in the earlier application.]